

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

U.S. <i>ex rel.</i> Tullio Emanuele,)	
)	
)	
Plaintiff/Relator,)	
v.)	C.A. No. 10-245 Erie
)	
Medicor Associates, <i>et al</i>,)	
)	
Defendants.)	
)	
)	

MEMORANDUM OPINION

Conti, Chief District Judge

Pending before the court are the Motion in Limine to Preclude Evidence or Bifurcate Trial (ECF No. 377) (“Motion to Preclude Evidence”) filed by defendants The Hamot Medical Center of the City of Erie (“Hamot”) and Medicor Associates, Inc. (“Medicor”, and together with Hamot, “Defendants”); the Motion in Limine to Preclude Reference to Any Burden of Proof Other than a Preponderance of the Evidence (ECF No. 398) (“Burden of Proof Motion”) filed by the United States *ex rel.* Tullio Emanuele (“Relator”); and Relator’s Motion in Limine Regarding the Measure of Damages under the False Claims Act (ECF No. 408) (“Damages Motion”). At a hearing held on October 12, 2017, the court ordered supplemental briefing on each of the three motions. Defendants filed a supplemental brief with respect to the Motion to Preclude Evidence (ECF No. 446) and the Burden of Proof Motion (ECF No. 448), but did not file a supplemental brief regarding the Damages Motion.¹ Relator responded to each filing (ECF Nos. 450, 451,

¹ Defendants also filed a supplemental brief (ECF No. 447) addressing Relator’s Motion to Preclude Reference to the

453), and the United States filed a Statement of Interest (ECF No. 455). These motions are now ripe for review.

I. Defendants' Motion to Preclude Evidence

Relator initiated this action pursuant to the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(C) (the “FCA”), which imposes liability on any person or entity who “knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1). In his amended complaint, Relator alleged that Defendants submitted claims to Medicare that violated the Stark Law, 42 U.S.C. § 1395nn, and the Anti-Kickback Act, 42 U.S.C. § 1320a-7b.² Both the Stark Law and the Anti-Kickback Act prohibit a health care entity from submitting claims to Medicare based upon referrals from physicians who have a “financial relationship” with the health care entity, unless a statutory or regulatory exception or safe harbor applies. 42 U.S.C. §§ 1395nn(a)(1); 1320a-7b(b). In the amended complaint, Relator alleged that there were financial relationships between Defendants and referrals from physicians as a result of those relationships which violated the Stark Law and Anti-Kickback Act. The amended complaint also pled that: (1) Defendants performed unnecessary medical procedures, often with fatal results; and (2) certain financial arrangements between Hamot and Medisor violated those statutes because they served no purpose but to facilitate the exchange of illegal referrals and kickbacks between Hamot and

Government’s Non-Intervention (ECF No. 386). Relator’s motion in limine with respect to the government’s non-intervention was granted. (Hearing Transcript 10/12/17 (ECF No. 442) at 56). At the hearing, the court denied defendants’ request to file a supplemental brief on that issue, but indicated that they could move for reconsideration “if [they] can find some case where it went to the jury and the court granted the motion or permitted [the government’s non-intervention] to come in as evidence.” (*Id.* at 56-57). Any such motion would have to meet the standards for reconsideration set forth in Federal Rule of Civil Procedure 59(e). Because no motion was filed, Relator’s motion to strike Defendants’ supplemental brief on this issue (ECF No. 449) will be granted.

²The analysis applicable to the Stark Law and Anti-Kickback Act is largely indistinguishable. *See Kosenske*, 554 F.3d at 91 (observing that “the requirements of the Anti-Kickback Act and its implementary regulations are indistinguishable from those of the Stark Act”).

Medicor. Relator alleged that these violations occurred “[f]rom at least June 1, 2001 through at least May 31, 2005, and beyond.” (*Id.* ¶ 2.)

Following discovery, Relator withdrew his allegations of unnecessary medical procedures. Relator continued to maintain that Defendants cannot meet their burden to show that the medical directorship arrangements satisfied any of the statutory exceptions (or safe harbors) set forth in the Stark Law and Anti-Kickback Act. He abandoned his argument that the medical directorships were “shams,” but argued that Defendants still could not satisfy any Stark Law or Anti-Kickback exceptions because some of their agreements were never reduced to writing or were permitted to lapse without written renewal.

In their Motion to Preclude Evidence, Defendants contend that the “allegations” that form the current basis for this litigation – to wit, that the contracts in issue governing the medical directorships were not in writing at all times as required by the Stark Law and Anti-Kickback Act – were never pleaded in either the original or amended complaint. Defendants seek to preclude Relator from offering any evidence to support these “unpleaded” claims and contends that this court lacks subject matter jurisdiction over them.³

To sustain a claim pursuant to § 3729(a)(1) of the FCA, a relator (or the government) must prove that (1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent. United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 304-05 (3d Cir. 2011); United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d

³ As a corollary to their assertion that Relator’s claims were never properly pled, Defendants’ maintain that it is now too late for Relator to amend his pleading to include these claims because the deadline for amendment was over three years ago. Defendants also argue that the court lacks subject-matter jurisdiction over any claims arising from documents turned over during discovery because Relator is not an original source with respect to those claims. Because Relator had personal knowledge concerning those claims based upon the financial relationships and referrals which continued after his employment ended, Defendants’ suggestion that he was not an original source as to those claims is without merit.

Cir. 2004). The relator must also establish that the alleged misrepresentation to the government was “material to the Government’s payment decision in order to be actionable under the False Claims Act.” Universal Health Services, Inc. v. U.S. ex rel. Escobar, 136 S.Ct. 1989, 2002 (2016). Where the allegedly false claims are based on violations of the Stark Law and the Anti-Kickback Act, the relator must prove that: (1) the defendants had a “financial relationship” of the type prohibited by the statute; (2) one of the defendants referred patients to the other for “designated health services”; and (3) claims based on those referrals were submitted to Medicare for payment. 42 U.S.C. § 1395nn(a)(1). Once the relator has established a *prima facie* violation of the Stark Law or the Anti-Kickback Act, the burden shifts to the defendants to demonstrate that the financial arrangement fits within a statutory exception or safe harbor. See United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 95 (3d Cir. 2009) (“Once the plaintiff or the government has established proof of each element of a violation under the [Stark] Act, the burden shifts to the defendant to establish that the conduct was protected by an exception.”); United States v. Rogan, 459 F.Supp.2d 692, 717 (N.D. Ill. 2006) (noting that, once the plaintiff or government has established a violation of the Stark Act, the defendant bears the burden of establishing that the conduct was protected by an exception); United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr., No. 09-1002, 2012 WL 921147, at *5 (M.D. Fla. Mar. 19, 2012) (because Stark Act exceptions are “affirmative defense rather than elements of a cause of action . . . it is the Defendants’ obligation to plead that they apply rather than the [relator’s] obligation to plead that they do not apply.”).

In his amended complaint, Relator alleged that Hamot and Medicor established a financial relationship by entering into “a series of contracts . . . to pay kickbacks . . . and to engage in unlawful relationships with physicians to induce patient referrals. (Amended

Complaint (ECF No. 64) ¶ 95.) Specifically, Relator alleged that Hamot and Medicor entered into “a series of sham contracts . . . for ‘medical directorships’ or other similar personal service arrangements.” (Id. ¶ 97.) Relator identified six medical directorships by name and averred that he had been personally assigned to provide services pursuant to one of them throughout his employment at Medicor. (Id. ¶¶ 98, 104.) Relator identified many of the critical terms of the arrangements, such as the timeframe, expectations for performance, compensation, and terms of renewal. (Id. ¶¶ 99-100.) Despite the existence of these financial arrangements, Relator averred that Medicor “referred thousands of patients covered by federal health insurance programs to Hamot on an exclusive basis.” (Id. ¶ 106.)

In addition to alleging the prima facie elements of his claim, Relator also alleged – although it was not his burden to do so – that the medical directorships did not satisfy the requirements of several of the Stark Law and Anti-Kickback Act exceptions that Defendants would most likely attempt to invoke. Relator alleged that these exceptions were not applicable because the directorship arrangements were “shams” that did not require Medicor physicians to perform any actual work, rendering the arrangements commercially unreasonable. (Amended Complaint (ECF No. 64) ¶¶ 116, 119-21.)

During discovery, evidence was adduced suggesting that the directorship arrangements may not always have been set forth “in writing,” as required by several Stark Law and Anti-Kickback Act exceptions. See 42 C.F.R. §411.357(l) (the “fair market value exception”); 42 C.F.R. § 411.357(d)(1) (“the personal services arrangements exception”). Relator moved for partial summary judgment on this basis. The court agreed with Relator that at least two medical directorships – the Women’s Heart Health directorship and the CV Chair arrangement – were never set forth in writing. (Summary Judgment Opinion (ECF No. 345) at 19-23.) The court

held that there were disputed issues of material fact about whether the remaining directorship agreements satisfied the writing requirement. (*Id.* at 19.) Significantly, the parties did not dispute the *prima facie* elements of Relator's Stark Law claims. (*Id.* at 12-13) ("The parties do not appear to dispute that a financial relationship existed among Hamot, Medicor, and the individual physician defendants. As such, the sole issue presented in Plaintiff's motion is whether the compensation arrangements satisfied one of the Stark Act exceptions during the relevant time periods.")

Defendants now contend that Relator should be precluded from offering any evidence to the jury regarding the writing requirement in certain exceptions contained in the Stark Law and Anti-Kickback Act because he never pled the absence of a written agreement in his amended complaint and that he was not the original source for that claim. Because the burden of establishing an applicable Stark Law or Anti-Kickback Act exception rests squarely with the defense, Defendants are essentially asking the Court to preclude Relator from offering evidence to refute the existence of a potential affirmative defense and to require the Relator to be an original source for the inapplicability of an affirmative defense.

In support of this proposition, Defendants rely heavily on Rockwell International Corp. v. United States, 549 U.S. 457 (2007), wherein a *qui tam* relator brought a False Claims Act ("FCA") action against a government contractor based on the contractor's operation of a nuclear weapons plant. *Id.* at 460. The relator, an engineer, had drafted a memorandum for the contractor, Rockwell International Corporation ("Rockwell"), explaining that a proposed method for disposing of toxic pond sludge would not work. *Id.* at 461. Rockwell intended to dispose of the sludge by mixing it with cement and turning it into solid "pondcrete" blocks. *Id.* The engineer explained that the proposed method of disposal relied on a piping system that would be

inadequate to remove the sludge in a form that could be turned into a solid block. Id. Rockwell proceeded with the project despite his objections. Id. After being laid off, the engineer, Stone, contacted the Federal Bureau of Investigation to inform it that Rockwell was concealing environmental violations. Id. at 462.

Based upon his “inadequate piping” theory, Stone initiated a FCA action alleging that Rockwell had falsely certified compliance with federal and state environmental regulations to induce the government to continue making payments on the contract. Id. at 463-64. The government later intervened and filed an amended complaint alleging that Rockwell had violated environmental laws by storing leaky pondcrete blocks. The government, however, did not allege that the pondcrete blocks were leaky for the same reason that Stone predicted (the inadequacy of the piping system). Id. at 465. Instead, the government alleged that the insolvency was due to an incorrect ratio of sludge to concrete, poor quality control, and inadequate inspections. Id.

Following a jury verdict in the government’s favor, Rockwell filed an appeal arguing that the government’s claims were based on publically disclosed allegations for which Stone was not an original source. Rockwell noted that federal courts lack jurisdiction over FCA allegations based on public disclosures “in a criminal, civil, or administrative hearing . . . or from the news media” unless the action is brought by the person who was the “original source of the information.” Id. at 467 (citing 31 U.S.C. 3730(e)(4)(A)). In order to be an original source, the relator must have “direct and independent knowledge of the information on which the allegations are based.” 31 U.S.C. § 3730(e)(4)(B). The Court ultimately determined that Stone’s allegations fell short of this standard:

Stone’s knowledge falls short. The only false claims ultimately found by the jury (and hence the only ones to which our jurisdictional inquiry is pertinent to the outcome) involved false statements with respect to environmental, safety, and health compliance over a 1 ½ year period

between April 1, 1987, and September 30, 1998. As described by Stone and the Government in the final pretrial order, the only pertinent problem with respect to this period of time for which Stone claimed to have direct and independent knowledge was insolid pondcrete. Because Stone was no longer employed by Rockwell at the time, he did not know that the pondcrete was insolid; he did not know that pondcrete storage was even subject to RCRA; he did not know that Rockwell would fail to remedy the defect; he did not know that the insolid pondcrete leaked while being stored onsite; and, of course, he did not know that Rockwell made false statements to the Government regarding pondcrete storage.

Id. at 475. Because Stone did not have “direct and independent knowledge of the information upon which his allegations were based,” the Court determined that the district court lacked jurisdiction over the claims arising from those allegations. Id. at 476.

Critically, the Court emphasized that the problem was not that Stone had incorrectly identified the source of the flaw in the pondcrete; rather, the problem was that Stone never actually knew whether the pondcrete had failed or not. He had simply predicted that it might.

The Court noted:

Stone’s prediction that the pondcrete would be insolid because of a flaw in the piping system does not qualify as “direct and independent knowledge” of the pondcrete defect. Of course a *qui tam* relator’s understanding of why a concealed defect occurred would normally be immaterial as long as he knew the defect actually existed. But here Stone did not *know* that the pondcrete failed; he *predicted* it. Even if a prediction can qualify as direct and independent knowledge in some cases (a point we need not address), it assuredly does not do so when its premise was a failed prediction, disproved by Stone’s own allegations.

Id. at 475-76 (emphasis in original).

The Court also rejected the government’s argument that Stone’s accurate allegations with respect to a totally different environmental violation (related to spray-irrigation) were sufficient to provide jurisdiction over all his claims:

Stone counters that his original-source status with respect to his spray-irrigation claim (which related to a time period different from that for his pondcrete claim) provided jurisdiction with respect to all of his claims.

We disagree. Section 3730(e)(4) does not permit jurisdiction in gross just because a relator is an original source with respect to some claim. We, along with every court to have addressed the question, conclude that § 3739(e)(4) does not permit such claim smuggling.

Id. at 476.

Defendants' contend that Rockwell is directly applicable. According to Defendants, Relator initially proffered one theory of liability (that the directorships were "shams") before shifting entirely to another theory (that the directorships were not properly reduced to writing). Defendant contends that Relator cannot "smuggle" his new "claims" into this action without independently establishing that he was the original source of those "claims."

Here, however, Relator's allegations with respect to the elements of his *prima facie* case, i.e. his claims, have never wavered. Relator's FCA claim requires him to demonstrate that the Defendants falsely and knowingly certified their compliance with the Stark Law and Anti-Kickback Act while submitting claims for payment to the government that were tainted by patient referrals between health care entities engaged in a financial relationship. As noted above, Relator's amended complaint contains reasonably detailed allegations that Hamot and Medicor knew about the prohibitions against illegal referrals and kickbacks under the Stark Law and Anti-Kickback Act, but entered into medical directorships for the purpose of inducing referrals and submitting claims for payment to the government based on those referrals. Indeed, the court granted partial summary judgment in favor of Relator on the inapplicability of an exception with respect to two medical directorship agreements.

Moreover, unlike in Rockwell, the theory that Relator purportedly failed to plead in his amended complaint – the absence of a written agreement – relates entirely to an affirmative defense on which Defendants bear the burden of proof. Defendants do not dispute that they bear the burden of demonstrating that a financial arrangement fits within an exception or safe harbor

to the Stark Law or Anti-Kickback Act. See Kosenske, 554 F.3d at 95 (“Once the plaintiff or the government has established proof of each element of a violation under the [Stark] Act, the burden shifts to the defendant to establish that the conduct was protected by an exception.”). To the extent that Relator initially pled that several of the Stark Law and Anti-Kickback Act exceptions did not apply because they were “shams,” that allegation went directly to an element that he had no obligation to plead at all. Relator’s failure to predict what potential defects might apply to the affirmative defenses raised by the Defendant is not the kind of “claim smuggling” contemplated by Rockwell.

Defendants respond that the scienter requirement of the FCA requires the Relator to go beyond his *prima facie* burden and allege precisely why Defendants’ financial arrangements did not satisfy a Stark Law or Anti-Kickback Act exception:

Relator’s Amended Complaint alleged a False Claims Act violation based on the theory that claims were false because Defendants’ financial arrangements based in the medical directorship agreements were shams. (Doc. 64, Am. Compl. ¶¶ 95-114). The only allegations relevant to Defendants’ knowledge (which Relator was obligated to plead a plausible basis for) were that Defendants knew their arrangements did not meet the Stark Law’s personal service and management contracts safe harbor. (Id. at ¶¶ 115-25). But now, Relator alleges a new reason why Defendants knew they were submitting false claims, i.e., that they knew their contracts were not in writing. This is a wholly separate allegation of and basis for Defendants’ scienter under the FCA and thus constitutes a separate claim, which under Rockwell requires a separate jurisdictional analysis.

(Defendants’ Supplemental Brief in Support (ECF No. 446) at 11.) Federal Rule of Civil Procedure 9(b), however, provides that “[m]alice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b); Smith v. Carolina Medical Center, No. 11-2756, 2017 WL 3310694, at *13-14 (E.D. Pa. Aug. 2, 2017) (noting that “general allegations” describing the scienter element of an FCA action are sufficient under Rule 9(b)).

The amended complaint alleges that Hamot and Medicor were “aware of the prohibitions against kickbacks and legal restrictions on financial relationships between hospitals and physicians” but nevertheless “entered into a series of contracts with Medicor” to induce patient referrals. (Amended Complaint (ECF No. 64) ¶ 95.) It also alleges that Hamot and Medicor “knowingly presented or caused to be presented” claims to Medicare for payment based on those referrals. (Id. ¶¶ 113-14.) These allegations were sufficient for purposes of the scienter requirement of Relator’s FCA claim. Smith, 2017 WL 3310694, at *13-14 (“[D]efendants argue that the government and relator fail to allege facts showing scienter. But knowledge “may be alleged generally under Rule 9(b).”).⁴

Defendants’ contention is also at odds with the well-established proposition that a relator does not bear the burden of establishing the absence of a Stark Law or Anti-Kickback Act exception. See Kosenske, 554 F.3d at 95. Indeed, it is axiomatic that a plaintiff has no obligation to “anticipate and answer” each of the potential affirmative defenses that might apply to his claim. VICI Racing, LLC v. T-Mobile USA, Inc., 763 F.3d 273, 301 (3d Cir. 2014). If the court were to adopt Defendants’ argument, a relator would be obligated to not only anticipate and plead a defendant’s lack of compliance with each and every Stark Law or Anti-Kickback Act exception, but also would need to plead the absence of each particular element of those exceptions. Rockwell - which did not involve the Stark Law or Anti-Kickback Act - simply cannot be read to support such a broad and novel proposition.

Finally, Defendants maintain that Relator’s allegations now focus on a time period that extended beyond his own employment with Medicor, involving transactions and patients about

⁴Moreover, once the elements of a claim “[have] been stated adequately, [they] may be supported by showing any set of facts consistent with the allegations in the complaint.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 563 (2007) (citing Sanjuan v. Am. Bd. of Psychiatry & Neurology, 40 F.3d 247, 251 (7th Cir. 1994)).

which he necessarily has no first-hand knowledge. Courts have rejected the premise that Rockwell creates an absolute bar to claims that stem from time periods outside a relator's time of employment. In United States ex rel. Galmines v. Novartis Pharmaceuticals Corp., for example, the court rejected this precise argument:

The holding in Rockwell was not—as Novartis contends—that the relator categorically could not be an original source for any allegations extending past the date of his employment. Rather, the Court held merely that the relator had no direct and independent knowledge of the facts underlying the fraudulent scheme. See U.S. ex rel. Hockett v. Columbia/HCA Healthcare Corp., 498 F.Supp.2d 25, 54 (D.D.C.2007) (“Under Rockwell, a relator must qualify as an original source for each distinct kind of claim or scheme she alleges.”). The relator predicted that the pondcrete would fail for one reason, then the relator was laid off, and then the pondcrete failed—but for an entirely different reason than the one the relator had predicted. Here, Mr. Galmines observed the off-label marketing and illegal kickbacks firsthand, then he left Novartis and filed this lawsuit, but the off-label marketing and illegal kickbacks continued as they had before he left Novartis. The analogous situation would have been if the relator in Rockwell observed the pondcrete failing, then brought a lawsuit and then left Rockwell, and the pondcrete continued to fail for the same reason the relator alleged in his lawsuit. Barring the relator in such a scenario from bringing a claim for the entire fraudulent scheme would not comport with common sense, the general principles of law, or the scheme of the False Claims Act. The key distinction in Rockwell was the fact that the relator had no direct and independent knowledge of the material facts underlying the actual fraudulent scheme—not that he was no longer employed at the company allegedly perpetrating the fraud.

Novartis, 88 F.Supp.3d 447, 452-53 (E.D. Pa. 2015). The same is true in the instant case.

Relator has consistently maintained that Hamot and Medicor entered into financial relationships designed to secure patient referrals while he was employed there and that the same kind of arrangements continued following his employment. As in Novartis, this allegation of a continuing fraud does not run afoul of the original source rule. Id. at 454-55 (noting that “the limitation on a relator’s ability to recover for additional periods of time is not the original source

bar but the pleading requirements and the discretionary powers of the court over discovery.”). Defendants’ motion to preclude evidence or bifurcate trial is denied.

II. Relator’s Burden of Proof Motion

In his Burden of Proof Motion, Relator contends that the applicable burden of proof for his FCA claims is a preponderance of the evidence, as in any other civil case. Defendants counter that claims premised on the Stark Law must be proven by clear and convincing evidence, while those premised on the Anti-Kickback Act must be proven beyond a reasonable doubt.

Prior to 1986, there was a divergence of authority in the circuit courts with respect to the applicable standard of proof in FCA cases. Compare United States v. Ueber, 299 F.2d 310 (6th Cir. 1962) (requiring clear and convincing evidence), and United States v. Foster Wheeler Corp., 447 F.2d 100 (2d Cir. 1971) (same), with United States v. Thomas, 709 F.2d 968 (5th Cir. 1983) (applying a preponderance of the evidence standard); Federal Crop Ins. Corp. v. Hester, 765 F.2d 723 (8th Cir. 1985) (same). In 1986, Congress addressed this divergence by amending the FCA to clarify that, “[i]n any action brought under section 3730, the United States shall be required to prove all essential elements of any cause of action, including damages, by a preponderance of the evidence.” 31 U.S.C. § 3731(d); see S. Rep. No. 96-615 at 8 (March 4, 1980) (noting the Senate Committee’s view that a burden of proof other than the preponderance of the evidence standard imposes an “unreasonably difficult standard[] of proof” in FCA actions and suggesting clarification by way of amendment). Defendants raise the novel argument that this revision applies only to actions brought by the United States, and not to actions brought a *qui tam* relator.

Defendants support their argument almost exclusively by citation to the United States Supreme Court’s decision in Graham County Soil & Water Conservation District v. United States ex rel. Wilson, 545 U.S. 409 (2005). In Graham, the Supreme Court observed in dicta that

“the context of [Section 3731(d)]” implies that the phrase “action brought under section 3730” is limited to “§ 3730(a) actions brought by the United States and § 3730(b) actions in which the United States intervenes as a party” *Id.* at 418. In the very next paragraph, the Court stated that the statute of limitation contained in Section 3731(b) applied only to Section 3730(a) and (b) actions without differentiating between those in which the government intervened and those in which it did not. *Id.* Defendants rely on Graham to suggest that the burden of proof set forth in Section 3731(d) should be limited to actions brought by the United States or in which the United States intervened. The only issue before the Court in Graham, however, was whether a relator’s retaliation claim under 31 U.S.C. § 3730(h) was governed by the three-year statute of limitations applicable to analogous state wrongful-discharge claims or the six-year period that the FCA prescribes for a “civil action under section 3730.” *Id.* at 417-18. Moreover, the provision that the Court was addressing – Section 3730(h) – creates a retaliation claim that is available only to a relator on his own behalf and does not involve the government. The applicable burden of proof in a § 3730(b) action brought on behalf of the United States by a relator was never an issue before the Court.

At the oral hearing, the court challenged the parties to produce relevant caselaw addressing the proper burden of proof, particularly in the context of jury instructions. Relator produced seven recent cases applying the “preponderance of the evidence” standard in either jury instructions or special verdict slips. *See, e.g., United States ex rel. Rigsby v. State Farm*, No. 1:06cv433 (S.D. Miss. 2016) (ECF No. 454-1) (incorporating the “preponderance of the evidence” standard into a special verdict form); *United States ex rel. Colquitt v. Abbott Laboratories*, No. 3:06cv1769 (N.D. Tx. Apr. 7, 2016) (ECF No. 454-2) (directing the jury to determine whether the relator proved his case “by a ‘preponderance of the evidence’”); *United*

States ex rel. Harman v. Trinity Industries, No. 2:12cv0089 (C.D. Tx. Oct. 20, 2014) (ECF No. 454-3) (special verdict form); United States ex rel. Ubl v. IIF Data Solutions, Inc., No. 1:06cv641 (E.D. Va. Oct. 27, 2008) (ECF No. 454-4) (special verdict form); United States ex rel. Ortolano v. Amin Radiology, No. 5:10cv583 (M.D. Fl. May 9, 2014) (ECF No. 454-5) (jury instructions); United States and State of Illinois ex rel. Absher v. Momence Meadows Nursing Center, No. 04-2289 (C.D. Ill. Feb. 8, 2013) (ECF No. 454-6) (jury instructions); United States ex rel. Loughren v. UnumProvident Corp., No. 03-11699 (D. Mass. Oct. 16, 2008) (ECF No. 454-7) (jury instructions). In contrast, Defendants failed to cite a single case actually applying a heightened burden of proof to a post-1986 FCA claim involving a relator. See St. Paul Fire and Marine Ins. Co. v. United States, 31 Fed. Cl. 151, 155 (Ct. Cl. 1994) (discussing the burden of proof in dicta in a non-FCA case but quoting the wrong statutory provision); United States v. Chilstead Building Company, Inc., 18 F.Supp.2d 210, 214 (relying on pre-1986 caselaw to apply a “clear and convincing” standard at the summary judgment stage in a case not involving a relator); United States v. Truong, 860 F.Supp.1137, 1140 (E.D. La. 1994) (discussing the pre-1986 split of authority in a non-relator case and concluding that the burden of proof had been met under either standard).

Based upon the foregoing, the court agrees with the courts that applied the preponderance of the evidence burden of proof in FCA cases, whether the action is brought by a relator on behalf of the United States or the United States government. See United States ex rel. Hyatt v. Northcrop Corp., 91 F.3d 1211, 1214-15 (9th Cir. 1996) (noting that the legislative history of the FCA “is replete with many instances in which the word ‘government’ is used when referring to suits brought in the name of the United States by . . . private *qui tam* plaintiffs” because “*qui tam* plaintiffs are merely agents suing on behalf of the government, which is always the real party in

interest”); United States v. Campbell, No. 08-1951, 2011 WL 43013, at *5 (D.N.J. Jan. 4, 2011) (applying the preponderance of the evidence standard to FCA claims brought on the basis of Stark and Anti-Kickback Act violations); United States v. Rogan, 459 F.Supp.2d 692, 716 n. 12 (N.D. Ill. 2006) (noting that the “criminality of predicate offenses in an underlying civil statute . . . does not mandate application of a higher burden of proof in a civil case”). Relator’s motion will be granted.

III. Relator’s Damages Motion

Finally, the parties disagree about whether any damages awarded to Relator for false claims must be offset by the value of any actual services performed by Hamot and Medicor physicians.⁵ Relator contends that the proper measure of damages is the full amount of any claims Hamot submitted to Medicare for payment that violated either the Stark Law or the Anti-Kickback Act. Defendants counter that the appropriate measure of damages in a FCA case is the difference between what the government paid and the value of the services the government actually received.

As correctly noted by Defendant, the traditional measure of damages in a FCA action is the difference between the market value of the product that the government received and the market value that the product would have been worth had it been of the specified quality. United States v. Bornstein, 423 U.S. 303, 316 n.13 (1976); see United States ex rel. Wall v. Circle C Construction, 813 F.3d 616, 618 (6th Cir. 2016) (rejecting the argument that the government should pay nothing for work performed on several buildings despite false claims); United States ex rel. Thomas v. Siemens AG, 991 F.Supp.2d 540, 573 (E.D. Pa. 2014) (measuring FCA damages “as the difference between what the government actually paid and what the government would have paid had it known of the falsity of the defendant’s claim”). This standard for damage

⁵ As previously noted, Defendants did not supply a supplemental brief on this issue.

calculation, often referred to as the “benefit of the bargain” standard, is typically applied where the government receives a tangible service or benefit. See Bornstein, 423 U.S. at 317 n. 13 (noting that the government’s damages after receiving deficient electron tubes for radio kits were “equal to the difference between the market value of the tubes it received and retained and the market value that the tubes would have had if they had been of the specified quality.”); Wall, 813 F.3d at 618 (offsetting the value of electrical work actually performed on government warehouses despite that the wages paid to electricians by the contractor violated a federal wage law).

In contrast, where the false claims at issue are based on illegal referrals or kickbacks, courts have typically awarded a full measure of damages under the principle that “the United States would have paid . . . nothing for hospital claims” tainted by violations of the Stark Law or Anti-Kickback Statute. United States v. Rogan, 517 F.3d 449, 453 (7th Cir. 2008). In Rogan, for example, the Court of Appeals for the Seventh Circuit held that the proper measure of damages where claims submitted to the United States are made false by kickbacks or illegal referrals is the full amount of each claim that was tainted by the illicit arrangement, despite that the patients may have actually received medical treatment:

“[We do not] think it important that most of the patients for which claims were submitted received some medical care – perhaps all the care reflected in the claim forms. . . . [Defendant] did not furnish any medical service to the United States. The government offers a subsidy (from the patients’ perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due. Thus the entire amount that [Defendant] received on these 1,812 claims must be paid back.”

Rogan, 517 F.3d at 453. In other words, no offset of damages is available because the government is explicitly barred by law from making *any* payment for a claim tainted by a kickback or illegal referral. Id. at 726; see United States ex rel. Wilkins v. United Health Group,

Inc., 659 F.3d 295, 314 (3d Cir. 2011) (noting that “[t]he government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback.”). Other courts have routinely reached the same conclusion in the kickback/illegal referral context. See, e.g., United States ex rel. Drakeford v. Tuomey, 792 F.3d 364, 386 (4th Cir. 2015) (“By reimbursing the [defendant hospital] for services that it was legally prohibited from paying [under the Stark Law], the government has suffered injury equivalent to the full amount of the payments.”); United States v. Mackby, 339 F.3d 1013, 1014-15 (9th Cir. 2003) (noting that, because Medicare fraud rendered the defendant ineligible to bill Medicare, the United States’ damages were the full sum of money that Medicare paid, despite that some services were actually performed); United States ex rel. Freedman v. Suarez-Hoyos, No. 04-933, 2012 WL 4344199, at *4 (M.D. Fla. Sept. 21, 2012) (concluding that “the amount of the Government’s damages resulting from the payment of false claims tainted by a kickback arrangement equals the full amount that Medicare paid on such claims”).

Defendants’ citation to United States ex rel. Nudelman v. International Rehab Associates, No. 00-1837, 2006 U.S. Dist. LEXIS 17958 (E.D. Pa. Apr. 4, 2006), does not compel a different result. In Nudelman, the relator claimed that the defendant was ineligible to bill the government for services because it had inaccurately represented that it was performing medical “utilization review” services that met a particular standard. Id. at *8-14. In reviewing a proposed settlement for fairness, the court was called upon to consider the potential range of possible recoveries for the relator. Id. at *53-54. The relator suggested that the maximum possible recovery would be the full value of all claims ever submitted under the contract, despite that fully complaint utilization reviews were performed in approximately 90-95% of the claims. Id. at *52. The court disagreed, opining that a more reasonable potential recovery would be the value of only

those claims that never actually received the contractually agreed-upon review process. Id. at *54. The court concluded that this analysis “has more logical appeal given that the traditional measure of damages in a false claims act case is the difference between the market value of what the government was promised and what it actually received. Id. (citing Bornstein, 423 U.S. at 316 n. 13).

Despite the court’s citation to Bornstein, a careful review of Nudelman actually supports relator’s position. The issue in Nudelman was not whether to offset the value of a single claim against the value of any service provided under that claim, but whether the entire body of claims submitted under a contract, both compliant and non-compliant, should be partitioned to account for only the non-compliant claims. Indeed, for each of the claims that the court determined was unlawful, the court considered damages based on the full value of that claim, with no offset. Id. at *54 (noting that a more reasonable potential recovery would be to deduct 95% from the total value paid for all claims to account for the 5% of claims that were unlawful).

In light of the foregoing, the court agrees with Relator that the proper measure of damages for services that the government is legally prohibited from paying due to illegal referrals or kickbacks is “equivalent to the full amount of the payments.” Drakeford, 792 F.3d at 387. Relator’s motion will be granted.

IV. Summary

For the reasons set forth herein, Defendants’ Motion in Limine to Preclude Evidence or Bifurcate Trial (ECF No. 377) is denied; Relator’s Motion in Limine to Preclude Reference to Any Burden of Proof Other than a Preponderance of the Evidence (ECF No. 398) is granted; Relator’s Motion in Limine Regarding the Measure of Damages under the False Claims Act

(ECF No. 408) is granted; and Relator's Motion to Strike (ECF No. 449) is granted. An appropriate order follows.

By the court:

/s/ Joy Flowers Conti
Joy Flowers Conti
Chief United States District Judge

Dated: October 26, 2017